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<b>(54) Title:</b> LIQUID ANTIMICROBIAL CLEANSING COMPOSITIONS  <b>(57) Abstract</b>  The present invention relates to a rinse-off antimicrobial cleansing composition comprising from about 0.1 % to about 5 % of an antimicrobial active, from about 8 % to about 18 % of an anionic surfactant, from about 2 % to about 12 % of a proton donating agent; from about 1 % to about 30 % of a lipophilic skin moisturizing agent; from about 0.1 % to about 4 % of a stabilizer; and from about 35 % to about 88.8 % of water. At least about 67 % of the anionic surfactant comprises a mixture of Class A and Class C surfactant. The weight ratio of Class A surfactant to Class C surfactant ranges from about 5:1 to about 1:2. The composition is adjusted to a pH of from about 3.5 to about 4.5.		

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## LIQUID ANTIMICROBIAL CLEANSING COMPOSITIONS

### TECHNICAL FIELD

The present invention relates to mild, rinse-off, personal cleansing compositions which provide enhanced antimicrobial effectiveness. Specifically, the personal cleansing compositions of the invention provide previously unseen residual effectiveness against transient Gram negative bacteria, improved levels of residual effectiveness against Gram positive bacteria and improved immediate reduction of germs on the skin upon use.

### BACKGROUND OF THE INVENTION

Human health is impacted by many microbial entities. Inoculation by viruses and bacteria cause a wide variety of sicknesses and ailments. Media attention to cases of food poisoning, strep infections, and the like is increasing public awareness of microbial issues.

It is well known that the washing of hard surfaces, food (e.g. fruit or vegetables) and skin, especially the hands, with antimicrobial or non-medicated soap, can remove many viruses and bacteria from the washed surfaces. Removal of the viruses and bacteria is due to the surfactancy of the soap and the mechanical action of the wash procedure. Therefore, it is known and recommended that the people wash frequently to reduce the spread of viruses and bacteria.

Bacteria found on the skin can be divided into two groups: resident and transient bacteria. Resident bacteria are Gram positive bacteria which are established as permanent microcolonies on the surface and outermost layers of the skin and play an important, helpful role in preventing the colonization of other, more harmful bacteria and fungi.

Transient bacteria are bacteria which are not part of the normal resident flora of the skin, but can be deposited when airborne contaminated material lands on the skin or when contaminated material is brought into physical contact with it. Transient bacteria are typically divided into two subclasses: Gram positive and Gram negative. Gram positive bacteria include pathogens such as *Staphylococcus aureus*, *Streptococcus pyogenes* and *Clostridium botulinum*. Gram negative bacteria include pathogens such as *Salmonella*, *Escherichia coli*, *Klebsiella*, *Haemophilus*, *Pseudomonas aeruginosa*, *Proteus* and *Shigella dysenteriae*. Gram negative bacteria are generally distinguished from Gram positive by an additional protective cell membrane which generally results in the Gram negative bacteria being less susceptible to topical antibacterial actives.

Antimicrobial cleansing products have been marketed in a variety of forms for some time. Forms include deodorant soaps, hard surface cleaners, and surgical disinfectants. These traditional rinse-off antimicrobial products have been formulated to provide bacteria removal during washing. The antimicrobial soaps have also been shown to provide a residual

effectiveness against Gram positive bacteria. By residual effectiveness it is meant that bacteria growth on a surface is controlled for some period of time following the washing/rinsing process. Antimicrobial liquid cleansers are disclosed in U.S. Patent Numbers: 4,847,072, Bissett et al., issued July 11, 1989, 4,939,284, Degenhardt, issued July 3, 1990 and 4,820,698, Degenhardt, issued April 11, 1989, all of which are incorporated herein by reference.

Previously marketed formulations of Head & Shoulders® Dandruff Shampoo, marketed until 1994, comprised anionic surfactants, an antibacterial active and citric acid as a pH adjuster. Head & Shoulders® controlled *Pityrosorum ovale* fungus, which causes dandruff. PCT application WO 92/18100, Keegan et al., published October 29, 1992 ("Keegan") and PCT application WO 95/32705, Fujiwara et al., published December 7, 1995 ("Fujiwara") teach liquid skin cleansers comprising mild surfactants, antibacterial agents and acidic compounds to buffer the pH, which provide improved germ hostility. However, the use of the low levels of acid compounds therein, result in compositions which do not deliver the undissociated acid required to provide residual effectiveness versus Gram negative bacteria. This situation is compounded in Keegan and Fujiwara by the preference of mild surfactants, including nonionic surfactants.

Some of these antimicrobial products, especially the hard surface cleaners and surgical disinfectants, utilize high levels of alcohol and/or surfactants which have been shown to dry out and irritate skin tissues. Ideal personal cleansers should gently cleanse the skin, cause little or no irritation, and not leave the skin or hair overly dry after frequent use and preferably should provide a moisturizing benefit to the skin.

U.S. Patent Number 3,141,821, issued to Compeau July 21, 1964 and Irgasan DP 300 (Triclosan®) technical literature from Ciba-Giegy, Inc., "Basic Formulation for Hand Disinfection 89/42/01" set forth antibacterial skin cleansers compositions which could provide residual effectiveness versus Gram negative bacteria using certain anionic surfactants, antimicrobial actives and acids. However, the selection, therein, of highly active surfactants results in personal cleansing compositions which are drying and harsh to the skin.

Given the severe health impacts of Gram negative bacteria like *Salmonella*, *Escherichia coli* and *Shigella*, it would be highly desirable to formulate antimicrobial cleansing compositions which provide residual effectiveness versus these Gram negative bacteria and which are mild to the skin. Existing consumer products have been unable to achieve both Gram negative residual effectiveness and mildness.

Applicants have found that rinse-off antimicrobial cleansing compositions which provide such mildness and such residual effectiveness versus Gram negative bacteria can be formulated by using known antimicrobial actives in combination with specific organic and/or inorganic acids as proton donating agents, and specific anionic surfactants, all of which are deposited on

the skin. The deposited proton donating agent and anionic surfactant enhance the selected active, to provide a new level of hostility to bacteria contacting the skin.

#### SUMMARY OF THE INVENTION

~~The present invention relates to a rinse-off antimicrobial cleansing composition~~ comprising from about 0.1% to about 5% of an antibacterial active; from about 8% to about 18% of anionic surfactant; from about 2% to about 12% of a proton donating agent; from about 1% to about 20% of a lipophilic skin moisturizing agent; from about 0.1% to about 4% of a stabilizer and from about 38% to about 88.8% of water. At least about 67% of the anionic surfactant comprises a mixture of Class A and Class C surfactants, wherein the weight ratio of Class A surfactants to Class C surfactants ranges from about 5:1 to about 1:2. The compositions of the present invention have a pH of from about 3.5 to about 4.5.

The present invention also relates to methods for cleansing and for decreasing the spread of transient Gram negative bacteria using the rinse-off antimicrobial cleansing compositions described herein.

#### DETAILED DESCRIPTION OF THE INVENTION

The rinse-off antimicrobial cleansing compositions of the present invention are highly efficacious for cleansing surfaces, especially the skin, provide a residual antimicrobial effectiveness versus transient Gram negative bacteria and are mild to the skin.

The term "rinse-off" is used herein to mean that the compositions of the present invention are used in a context whereby the composition is ultimately rinsed or washed from the treated surface, (e.g., skin or hard surfaces) either after or during the application of the product.

The term "antimicrobial cleansing composition" as used herein means a composition suitable for application to a surface for the purpose of removing dirt, oil and the like which additionally controls the growth and colonization of transient Gram negative bacteria. Preferred embodiments of the present invention are cleansing compositions suitable for use on the human skin.

The compositions of the present invention can also be useful for treatment of acne. As used herein "treating acne" means preventing, retarding and/or arresting the process of acne formation in mammalian skin.

The compositions of the invention can also potentially be useful for providing an essentially immediate (i.e., acute) visual improvement in skin appearance following application of the composition to the skin. More particularly, the compositions of the present invention are useful for regulating skin condition, including regulating visible and/or tactile discontinuities in skin, including but not limited to visible and/or tactile discontinuities in skin texture and/or color, more especially discontinuities associated with skin aging. Such discontinuities may be induced or caused by internal and/or external factors. Extrinsic factors include ultraviolet

radiation (e.g., from sun exposure), environmental pollution, wind, heat, low humidity, harsh surfactants, abrasives, and the like. Intrinsic factors include chronological aging and other biochemical changes from within the skin.

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~~Regulating skin condition includes prophylactically and/or therapeutically regulating~~ skin condition. As used herein, prophylactically regulating skin condition includes delaying, minimizing and/or preventing visible and/or tactile discontinuities in skin. As used herein, therapeutically regulating skin condition includes ameliorating, e.g., diminishing, minimizing and/or effacing, such discontinuities. Regulating skin condition involves improving skin appearance and/or feel, e.g., providing a smoother, more even appearance and/or feel. As used herein, regulating skin condition includes regulating signs of aging. "Regulating signs of skin aging" includes prophylactically regulating and/or therapeutically regulating one or more of such signs (similarly, regulating a given sign of skin aging, e.g., lines, wrinkles or pores, includes prophylactically regulating and/or therapeutically regulating that sign).

"Signs of skin aging" include, but are not limited to, all outward visibly and tactilely perceptible manifestations as well as any other macro or micro effects due to skin aging. Such signs may be induced or caused by intrinsic factors or extrinsic factors, e.g., chronological aging and/or environmental damage. These signs may result from processes which include, but are not limited to, the development of textural discontinuities such as wrinkles, including both fine superficial wrinkles and coarse deep wrinkles, skin lines, crevices, bumps, large pores (e.g., associated with adnexal structures such as sweat gland ducts, sebaceous glands, or hair follicles), scaliness, flakiness and/or other forms of skin unevenness or roughness, loss of skin elasticity (loss and/or inactivation of functional skin elastin), sagging (including puffiness in the eye area and jowls), loss of skin firmness, loss of skin tightness, loss of skin recoil from deformation, discoloration (including undereye circles), blotching, sallowness, hyperpigmented skin regions such as age spots and freckles, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown, and other histological changes in the stratum corneum, dermis, epidermis, the skin vascular system (e.g., telangiectasia or spider vessels), and underlying tissues, especially those proximate to the skin.

All percentages and ratios used herein, unless otherwise indicated, are by weight and all measurements made are at 25°C, unless otherwise designated. The invention hereof can comprise, consist of, or consist essentially of, the essential as well as optional ingredients and components described therein.

## **I. INGREDIENTS**

The rinse-off antimicrobial cleansing compositions of the present invention comprise Triclosan®, an anionic surfactant, a proton donating agent, a lipophilic skin moisturizing agent, a stabilizer and water. Each of these ingredients is described in detail as follows.

#### A. ANTIMICROBIAL ACTIVE

The rinse-off antimicrobial cleansing compositions of the present invention comprise from about 0.1% to about 5%, preferably from about 0.1% to about 2%, more preferably from about 0.1% to about 1% of an antimicrobial active. Non-cationic actives are required in order to avoid interaction with the anionic surfactants of the invention.

Given below are examples of non-cationic antimicrobial agents which are useful in the present invention .

Pyrrithiones, especially the zinc complex (ZPT)  
Octopirox®  
Dimethyldimethylol Hydantoin (Glydant®)  
Methylchloroisothiazolinone/methylisothiazolinone (Kathon CG®)  
Sodium Sulfite  
Sodium Bisulfite  
Imidazolidinyl Urea (Germall 115®)  
Diazolidinyl Urea (Germall II®)  
Benzyl Alcohol  
2-Bromo-2-nitropropane-1,3-diol (Bronopol®)  
Formalin (formaldehyde)  
Iodopropenyl Butylcarbamate (Polyphase P100®)  
Chloroacetamide  
Methanamine  
Methyldibromonitrile Glutaronitrile (1,2-Dibromo-2,4-dicyanobutane or Tektamer®)  
Glutaraldehyde  
5-bromo-5-nitro-1,3-dioxane (Bronidox®)  
Phenethyl Alcohol  
o-Phenylphenol/sodium o-phenylphenol  
Sodium Hydroxymethylglycinate (Suttocide A®)  
Polymethoxy Bicyclic Oxazolidine (Nuosept C®)  
Dimethoxane  
Thimersal  
Dichlorobenzyl Alcohol  
Captan  
Chlorphenenesin  
Dichlorophene  
Chlorbutanol  
Glyceryl Laurate  
Halogenated Diphenyl Ethers  
    2,4,4'-trichloro-2'-hydroxy-diphenyl ether (Triclosan® or TCS)  
    2,2'-dihydroxy-5,5'-dibromo-diphenyl ether  
Phenolic Compounds  
    Phenol  
    2-Methyl Phenol  
    3-Methyl Phenol

4-Methyl Phenol  
4-Ethyl Phenol  
2,4-Dimethyl Phenol  
2,5-Dimethyl Phenol  
3,4-Dimethyl Phenol  
2,6-Dimethyl Phenol  
4-n-Propyl Phenol  
4-n-Butyl Phenol  
4-n-Amyl Phenol  
4-tert-Amyl Phenol  
4-n-Hexyl Phenol  
4-n-Heptyl Phenol

Mono- and Poly-Alkyl and Aromatic Halophenols

p-Chlorophenol  
Methyl p-Chlorophenol  
Ethyl p-Chlorophenol  
n-Propyl p-Chlorophenol  
n-Butyl p-Chlorophenol  
n-Amyl p-Chlorophenol  
sec-Amyl p-Chlorophenol  
n-Hexyl p-Chlorophenol  
Cyclohexyl p-Chlorophenol  
n-Heptyl p-Chlorophenol  
n-Octyl p-Chlorophenol  
o-Chlorophenol  
Methyl o-Chlorophenol  
Ethyl o-Chlorophenol  
n-Propyl o-Chlorophenol  
n-Butyl o-Chlorophenol  
n-Amyl o-Chlorophenol  
tert-Amyl o-Chlorophenol  
n-Hexyl o-Chlorophenol  
n-Heptyl o-Chlorophenol  
o-Benzyl p-Chlorophenol  
o-Benzyl-m-methyl p-Chlorophenol  
o-Benzyl-m, m-dimethyl p-Chlorophenol  
o-Phenylethyl p-Chlorophenol  
o-Phenylethyl-m-methyl p-Chlorophenol  
3-Methyl p-Chlorophenol  
3,5-Dimethyl p-Chlorophenol  
6-Ethyl-3-methyl p-Chlorophenol  
6-n-Propyl-3-methyl p-Chlorophenol  
6-iso-Propyl-3-methyl p-Chlorophenol  
2-Ethyl-3,5-dimethyl p-Chlorophenol  
6-sec-Butyl-3-methyl p-Chlorophenol  
2-iso-Propyl-3,5-dimethyl p-Chlorophenol  
6-Diethylmethyl-3-methyl p-Chlorophenol  
6-iso-Propyl-2-ethyl-3-methyl p-Chlorophenol  
2-sec-Amyl-3,5-dimethyl p-Chlorophenol  
2-Diethylmethyl-3,5-dimethyl p-Chlorophenol



6-sec-Octyl-3-methyl p-Chlorophenol

p-Chloro-m-cresol

p-Bromophenol

Methyl p-Bromophenol

Ethyl p-Bromophenol

n-Propyl p-Bromophenol

n-Butyl p-Bromophenol

n-Amyl p-Bromophenol

sec-Amyl p-Bromophenol

n-Hexyl p-Bromophenol

Cyclohexyl p-Bromophenol

o-Bromophenol

tert-Amyl o-Bromophenol

n-Hexyl o-Bromophenol

n-Propyl-m,m-Dimethyl o-Bromophenol

2-Phenyl Phenol

4-Chloro-2-methyl phenol

4-Chloro-3-methyl phenol

4-Chloro-3,5-dimethyl phenol

2,4-Dichloro-3,5-dimethylphenol

3,4,5,6-Terabromo-2-methylphenol

5-Methyl-2-pentylphenol

4-Isopropyl-3-methylphenol

Para-chloro-meta-xylene (PCMX)

Chlorothymol

Phenoxyethanol

Phenoxyisopropanol

5-Chloro-2-hydroxydiphenylmethane

#### Resorcinol and its Derivatives

Resorcinol

Methyl Resorcinol

Ethyl Resorcinol

n-Propyl Resorcinol

n-Butyl Resorcinol

n-Amyl Resorcinol

n-Hexyl Resorcinol

n-Heptyl Resorcinol

n-Octyl Resorcinol

n-Nonyl Resorcinol

Phenyl Resorcinol

Benzyl Resorcinol

Phenylethyl Resorcinol

Phenylpropyl Resorcinol

p-Chlorobenzyl Resorcinol

5-Chloro 2,4-Dihydroxydiphenyl Methane

4'-Chloro 2,4-Dihydroxydiphenyl Methane

5-Bromo 2,4-Dihydroxydiphenyl Methane

4' -Bromo 2,4-Dihydroxydiphenyl Methane

#### Bisphenolic Compounds

2,2'-Methylene bis (4-chlorophenol)

2,2'-Methylene bis (3,4,6-trichlorophenol)  
 2,2'-Methylene bis (4-chloro-6-bromophenol)  
 bis (2-hydroxy-3,5-dichlorophenyl) sulphide  
 bis (2-hydroxy-5-chlorobenzyl)sulphide

**Benzoic Esters (Parabens)**

Methylparaben  
 Propylparaben  
 Butylparaben  
 Ethylparaben  
 Isopropylparaben  
 Isobutylparaben  
 Benzylparaben  
 Sodium Methylparaben  
 Sodium Propylparaben

**Halogenated Carbanilides**

3,4,4'-Trichlorocarbanilides (Triclocarban® or TCC)  
 3-Trifluoromethyl-4,4'-dichlorocarbanilide  
 3,3',4'-Trichlorocarbanilide

Another class of antibacterial agents, which are useful in the present invention, are the so-called "natural" antibacterial actives, referred to as natural essential oils. These actives derive their names from their natural occurrence in plants. Typical natural essential oil antibacterial actives include oils of anise, lemon, orange, rosemary, wintergreen, thyme, lavender, cloves, hops, tea tree, citronella, wheat, barley, lemongrass, cedar leaf, cedarwood, cinnamon, fleagrass, geranium, sandalwood, violet, cranberry, eucalyptus, vervain, peppermint, gum benzoin, basil, fennel, fir, balsam, menthol, ocmea origanum, *Hydastis carradensis*, *Berberidaceae daceae*, *Ratanhia* and *Curcuma longa*. Also included in this class of natural essential oils are the key chemical components of the plant oils which have been found to provide the antimicrobial benefit. These chemicals include, but are not limited to anethol, catechole, camphene, thymol, eugenol, eucalyptol, ferulic acid, farnesol, hinokitol, tropolone, limonene, menthol, methyl salicylate, thymol, terpeneol, verbenone, berberine, ratanhia extract, caryophellene oxide, citronellic acid, curcumin, nerolidol and geraniol.

Additional active agents are antibacterial metal salts. This class generally includes salts of metals in groups 3b-7b, 8 and 3a-5a. Specifically are the salts of aluminum, zirconium, zinc, silver, gold, copper, lanthanum, tin, mercury, bismuth, selenium, strontium, scandium, yttrium, cerium, praseodymium, neodymium, promethum, samarium, europium, gadolinium, terbium, dysprosium, holmium, erbium, thulium, ytterbium, lutetium and mixtures thereof.

Preferred antimicrobial agents for use herein are the broad spectrum actives selected from the group consisting of Triclosan®, Triclocarban®, Octopirox®, PCMX, ZPT, natural essential oils and their key ingredients, and mixtures thereof. The most preferred antimicrobial active for use in the present invention is Triclosan®

**B. ANIONIC SURFACTANT**

The rinse-off antimicrobial cleansing compositions of the present invention comprise from about 8% to about 18%, preferably from about 8% to about 16%, and more preferably from about 8% to about 12%, based on the weight of the personal cleansing composition, of anionic surfactant. Without being limited by theory, it is believed that the anionic surfactant disrupts the lipid in the cell membrane of the bacteria. The particular acid used herein reduces the negative charges on the cell wall of the bacteria, crosses through the cell membrane, weakened by the surfactant, and acidifies the cytoplasm of the bacteria. The antimicrobial active can then pass more easily through the weakened cell wall, and more efficiently poison the bacteria.

Nonlimiting examples of anionic lathering surfactants useful in the compositions of the present invention are disclosed in McCutcheon's, Detergents and Emulsifiers, North American edition (1990), published by The Manufacturing Confectioner Publishing Co.; McCutcheon's, Functional Materials, North American Edition (1992); and U.S. Patent No. 3,929,678, to Laughlin et al., issued December 30, 1975, all of which are incorporated by reference.

A wide variety of anionic surfactants are potentially useful herein. Nonlimiting examples of anionic lathering surfactants include those selected from the group consisting of alkyl and alkyl ether sulfates, sulfated monoglycerides, sulfonated olefins, alkyl aryl sulfonates, primary or secondary alkane sulfonates, alkyl sulfosuccinates, acyl taurates, acyl isethionates, alkyl glycerylether sulfonate, sulfonated methyl esters, sulfonated fatty acids, alkyl phosphates, acyl glutamates, acyl sarcosinates, alkyl sulfoacetates, acylated peptides, alkyl ether carboxylates, acyl lactylates, anionic fluorosurfactants, and mixtures thereof. Mixtures of anionic surfactants can be used effectively in the present invention.

Anionic surfactants for use in the cleansing compositions include alkyl and alkyl ether sulfates. These materials have the respective formulae  $R^1O-SO_3M$  and  $R^1(CH_2H_4O)_x-O-SO_3M$ , wherein  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl group from about 8 to about 24 carbon atoms,  $x$  is 1 to 10, and  $M$  is a water-soluble cation such as ammonium, sodium, potassium, magnesium, triethanolamine, diethanolamine and monoethanolamine. The alkyl sulfates are typically made by the sulfation of monohydric alcohols (having from about 8 to about 24 carbon atoms) using sulfur trioxide or other known sulfation technique. The alkyl ether sulfates are typically made as condensation products of ethylene oxide and monohydric alcohols (having from about 8 to about 24 carbon atoms) and then sulfated. These alcohols can be derived from fats, e.g., coconut oil or tallow, or can be synthetic. Specific examples of alkyl sulfates which may be used in the cleanser compositions are sodium, ammonium, potassium, magnesium, or TEA salts of lauryl or myristyl sulfate. Examples of alkyl ether sulfates which may be used include ammonium, sodium, magnesium, or TEA laureth-3 sulfate.

Another suitable class of anionic surfactants are the sulfated monoglycerides of the form  $R^1CO-O-CH_2-C(OH)H-CH_2-O-SO_3M$ , wherein  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl group from about 8 to about 24 carbon atoms, and M is a water-soluble cation such as ammonium, sodium, potassium, magnesium, triethanolamine, diethanolamine and monoethanolamine. These are typically made by the reaction of glycerin with fatty acids (having from about 8 to about 24 carbon atoms) to form a monoglyceride and the subsequent sulfation of this monoglyceride with sulfur trioxide. An example of a sulfated monoglyceride is sodium cocomonoglyceride sulfate.

Other suitable anionic surfactants include olefin sulfonates of the form  $R^1SO_3M$ , wherein  $R^1$  is a mono-olefin having from about 12 to about 24 carbon atoms, and M is a water-soluble cation such as ammonium, sodium, potassium, magnesium, triethanolamine, diethanolamine and monoethanolamine. These compounds can be produced by the sulfonation of alpha olefins by means of uncomplexed sulfur trioxide, followed by neutralization of the acid reaction mixture in conditions such that any sultones which have been formed in the reaction are hydrolyzed to give the corresponding hydroxyalkanesulfonate. An example of a sulfonated olefin is sodium C<sub>14</sub>-C<sub>16</sub> alpha olefin sulfonate.

Other suitable anionic surfactants are the linear alkylbenzene sulfonates of the form  $R^1-C_6H_4-SO_3M$ , wherein  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl group from about 8 to about 24 carbon atoms, and M is a water-soluble cation such as ammonium, sodium, potassium, magnesium, triethanolamine, diethanolamine and monoethanolamine. These are formed by the sulfonation of linear alkyl benzene with sulfur trioxide. An example of this anionic surfactant is sodium dodecylbenzene sulfonate.

Still other anionic surfactants suitable for this cleansing composition include the primary or secondary alkane sulfonates of the form  $R^1SO_3M$ , wherein  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl chain from about 8 to about 24 carbon atoms, and M is a water-soluble cation such as ammonium, sodium, potassium, magnesium, triethanolamine, diethanolamine and monoethanolamine. These are commonly formed by the sulfonation of paraffins using sulfur dioxide in the presence of chlorine and ultraviolet light or another known sulfonation method. The sulfonation can occur in either the secondary or primary positions of the alkyl chain. An example of an alkane sulfonate useful herein is alkali metal or ammonium C<sub>13</sub>-C<sub>17</sub> paraffin sulfonates.

Still other suitable anionic surfactants are the alkyl sulfosuccinates, which include disodium N-octadecylsulfosuccinamate; diammonium lauryl sulfosuccinate; tetrasodium N-(1,2-dicarboxyethyl)-N-octadecylsulfosuccinate; diamyl ester of sodium sulfosuccinic acid; dihexyl ester of sodium sulfosuccinic acid; and dioctyl esters of sodium sulfosuccinic acid.

Also useful are taurates which are based on taurine, which is also known as 2-aminoethanesulfonic acid. Examples of taurates include N-alkyltaurines such as the one prepared by reacting dodecylamine with sodium isethionate according to the teaching of U.S. Patent 2,658,072 which is incorporated herein by reference in its entirety. Other examples based of taurine include the acyl taurines formed by the reaction of n-methyl taurine with fatty acids (having from about 8 to about 24 carbon atoms).

Another class of anionic surfactants suitable for use in the cleansing composition are the acyl isethionates. The acyl isethionates typically have the formula  $R^1CO-O-CH_2CH_2SO_3M$  wherein  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl group having from about 10 to about 30 carbon atoms, and M is a cation. These are typically formed by the reaction of fatty acids (having from about 8 to about 30 carbon atoms) with an alkali metal isethionate. Nonlimiting examples of these acyl isethionates include ammonium cocoyl isethionate, sodium cocoyl isethionate, sodium lauroyl isethionate, and mixtures thereof.

Still other suitable anionic surfactants are the alkylglyceryl ether sulfonates of the form  $R^1-OCH_2-C(OH)H-CH_2-SO_3M$ , wherein  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl group from about 8 to about 24 carbon atoms, and M is a water-soluble cation such as ammonium, sodium, potassium, magnesium, triethanolamine, diethanolamine and monoethanolamine. These can be formed by the reaction of epichlorohydrin and sodium bisulfite with fatty alcohols (having from about 8 to about 24 carbon atoms) or other known methods. One example is sodium cocoglyceryl ether sulfonate.

Other suitable anionic surfactants include the sulfonated fatty acids of the form  $R^1-CH(SO_4)-COOH$  and sulfonated methyl esters of the form  $R^1-CH(SO_4)-CO-O-CH_3$ , where  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl group from about 8 to about 24 carbon atoms. These can be formed by the sulfonation of fatty acids or alkyl methyl esters (having from about 8 to about 24 carbon atoms) with sulfur trioxide or by another known sulfonation technique. Examples include alpha sulphonated coconut fatty acid and lauryl methyl ester.

Other anionic materials include phosphates such as monoalkyl, dialkyl, and trialkylphosphate salts formed by the reaction of phosphorous pentoxide with monohydric branched or unbranched alcohols having from about 8 to about 24 carbon atoms. These could also be formed by other known phosphorylation methods. An example from this class of surfactants is sodium mono or dilaurylphosphate.

Other anionic materials include acyl glutamates corresponding to the formula  $R^1CO-N(COOH)-CH_2CH_2-CO_2M$  wherein  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl or alkenyl group of about 8 to about 24 carbon atoms, and M is a water-soluble cation. Nonlimiting examples of which include sodium lauroyl glutamate and sodium cocoyl glutamate.

Other anionic materials include alkanoyl sarcosinates corresponding to the formula  $R^1\text{CON}(\text{CH}_3)\text{-CH}_2\text{CH}_2\text{-CO}_2\text{M}$  wherein  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl or alkenyl group of about 10 to about 20 carbon atoms, and M is a water-soluble cation. ~~Nonlimiting examples of which include sodium lauroyl sarcosinate, sodium cocoyl sarcosinate, and ammonium lauroyl sarcosinate.~~

Other anionic materials include alkyl ether carboxylates corresponding to the formula  $R^1\text{-(OCH}_2\text{CH}_2)_x\text{-OCH}_2\text{-CO}_2\text{M}$  wherein  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl or alkenyl group of about 8 to about 24 carbon atoms, x is 1 to 10, and M is a water-soluble cation. Nonlimiting examples of which include sodium laureth carboxylate.

Other anionic materials include acyl lactylates corresponding to the formula  $R^1\text{CO-[O-CH(CH}_3\text{)-CO]}_x\text{-CO}_2\text{M}$  wherein  $R^1$  is a saturated or unsaturated, branched or unbranched alkyl or alkenyl group of about 8 to about 24 carbon atoms, x is 3, and M is a water-soluble cation. Nonlimiting examples of which include sodium cocoyl lactylate.

Other anionic materials include the carboxylates, nonlimiting examples of which include sodium lauroyl carboxylate, sodium cocoyl carboxylate, and ammonium lauroyl carboxylate. Anionic fluorsurfactants can also be used.

Any counter cation, M, can be used on the anionic surfactant. Preferably the counter cation is selected from the group consisting of sodium, potassium, ammonium, monoethanolamine, diethanolamine, and triethanolamine. More preferably the counter cation is ammonium.

Although any of these surfactants can be employed in the liquid antimicrobial cleansing compositions herein, at least about 67%, preferably at least about 80% and most preferably at least about 90% of the anionic surfactant present in the liquid antimicrobial compositions herein comprises a mixture of Class A and Class C surfactants as hereinafter defined. The weight ratio of Class A surfactants to Class C surfactants ranges from about 5:1 to about 1:2, preferably from about 4:1 to about 1:1.

The anionic surfactants primarily employed in the compositions of the present invention can be grouped into four classes based on their mildness and antimicrobial efficacy. The four classes of anionic surfactants are defined below.

**Class A** - The first class of anionic surfactants are those which are considered to be mild, but minimally enhance antimicrobial efficacy. These includes the group consisting of alkyl ether sulfates; acyl monoglyceryl sulfates; alkyl glycerylether sulfonates; acyl isethionates; acyl taurates; alkyl sulfosuccinates; alkyl sulfoacetates; sulfonated olefins; alkyl sulfates which have a predominant chain length of C8, C10, C16 or C18; and mixtures thereof.

**Class B** - The second class of surfactants are those which are considered to be mild, but enhance antimicrobial efficacy. These includes the group consisting of primary or secondary

alkane sulfonates, alkyl sulfates which have a predominant chain length of C14, and mixtures thereof.

Class C - The third class of anionic surfactants are those which are considered to be harsh, but which greatly enhance antimicrobial efficacy. These include the group consisting of alkyl aryl sulfonates, alkyl sulfocarboxylates, sulfonated fatty acids, alkyl phosphates, alkyl sulfates which have a predominant chain length of C12, and mixtures thereof. Specific examples of harsh surfactants are lauryl sulfate, lauryl benzene sulfonate, monolauryl phosphate, and lauryl sulfocarboxylate.

Class D - The fourth class of surfactants consist of surfactants which have a pKa of greater than 4.0. These surfactants have been generally found to be mild and very efficacious. They include the group consisting of acyl sarcosinates, acyl glutamates, alkyl ether carboxylates and mixtures thereof.

Non-anionic surfactants of the group consisting of nonionic surfactants, cationic surfactants, amphoteric surfactants and mixtures thereof, have been found to actually inhibit residual effectiveness benefits when used with anionic surfactants at high levels. This is most evident in the case of cationic and amphoteric surfactants where it is believed that these surfactants interfere with the anionic surfactant's ability to disrupt of the lipid in the cell membrane (charge-charge interaction). The ratio of the amount of these non-anionic surfactants to the amount of anionic surfactant should be less than 1:1, preferably less than 1:2, and more preferably less than 1:4 in the compositions herein.

The rinse-off antimicrobial cleansing compositions of the present invention preferably do not comprise hydrotropic sulfonates, particularly salts of terpenoids, or mono- or binuclear aromatic compounds such as sulfonates of camphor, toluene, xylene, cumene and naphthene.

#### C. PROTON DONATING AGENT

The rinse-off antimicrobial cleansing compositions of the present invention comprise from about 2% to about 12%, preferably from about 2% to about 10%, more preferably from about 2% to about 9%, and most preferably from about 4% to about 9% based on the weight of the personal cleansing composition, of a proton donating agent. By "proton donating agent" it is meant any acid compound or mixture thereof, which results in the presence of undissociated acid on the skin after use. Proton donating agents can be organic acids, including polymeric acids, mineral acids or mixtures thereof.

##### Organic Acids

Proton donating agents which are organic acids remain at least partially undissociated in the neat composition and remain so when the compositions are diluted during washing and rinsing. The organic acid proton donating agent must have at least one pKa value below 5.5. These organic proton donating agents can be added directly to the composition in the acid form

or can be formed by adding the conjugate base of the desired acid and a sufficient amount of a separate acid strong enough to form the undissociated acid from the base.

#### Biological Activity Index of Organic Acids

~~Preferred organic proton-donating agents are selected based on their biological activity.~~

This activity is represented by a Biological Activity Index, Z, which is defined as:

$$Z = 1 + 0.25pK_{a1} + 0.42\log P.$$

The biological activity index combines the dissociation characteristics and the hydrophobicity of the acid. It is critical that the undissociated proton donating agent of the composition be deposited on the skin to reduce the negative charge on the cell wall. The acid's dissociation constant,  $pK_{a1}$ , is indicative of the chemical's proton donating capacity relative to the pH of the medium in which it is incorporated. Since more undissociated acid is preferable in the composition, acids with higher  $pK_a$ 's are generally more preferred for a given product pH. The octanol-water partition coefficient, P, represents the tendency of materials in solution to prefer either oils or water. It essentially is a measure of hydrophobic nature of a material in solution: the higher the partition coefficient, the more oil soluble, and less water soluble, the material. Since it is desired that the dissolved acids in the compositions come out of the aqueous cleanser upon application, deposit on the oil-based skin and remain during rinsing, organic acids with higher octanol-water partition coefficients are more preferred.

Preferred organic proton donating agents of the rinse-off antimicrobial cleansing compositions of the present invention have a biological activity index greater than about 0.75, preferably greater than about 1.0, more preferably greater than about 1.5 and most preferably greater than 2.0.

#### Mineral Acids

Proton donating agents which are mineral acids will not remain undissociated in the neat composition or when the compositions are diluted during washing and rinsing. Despite this, it has been found that mineral acids can be effective proton donating agents for use herein. Without being limited by theory, it is believed that the strong mineral acids, protonate the carboxylic and phosphatidyl groups in proteins of the skin cells, thereby providing *in-situ* undissociated acid. These proton donating agents can only be added directly to the composition in the acid form.

#### pH

It is critical to achieving the benefits of the invention that the undissociated acid from the proton donating agent (deposited or formed *in-situ*) remain on the skin in the protonated form. Therefore, the pH of the rinse-off antimicrobial cleansing compositions of the present invention must be adjusted to a sufficiently low level in order to either form or deposit substantial undissociated acid on the skin. The pH of the compositions should be adjusted and preferably



buffered to within the range of from about 3.0 to about 5.5, preferably from about 3.5 to about 4.5.

A non-exclusive list of examples of organic acids which can be used as the proton donating agent are adipic, tartaric, citric, maleic, malic, succinic, glycolic, glutaric, benzoic, malonic, salicylic, gluconic, polyacrylic acid and mixtures thereof. When salicylic acid is used included in the compositions herein, it is used at a level ranging from about 0.15% to about 2% by weight of the composition. A non-exclusive list of examples of mineral acid for use herein are hydrochloric, phosphoric, sulfuric and mixtures thereof.

#### D. LIPOPHILIC SKIN MOISTURIZING AGENT

The liquid, rinse-off antimicrobial personal cleansing compositions herein comprise from about 1% to about 30%, preferably from about 3% to about 25%, most preferably from about 5% to about 25% of a lipophilic skin moisturizing agent. It has been found that compositions which contain a lipophilic skin moisturizing agent have improved antibacterial efficacy compared to compositions which do not contain a lipophilic skin moisturizing agent. In addition, the lipophilic skin moisturizing agent provides a moisturizing benefit to the user of the personal cleansing product when the lipophilic skin moisturizing agent is deposited to the user's skin.

Two types of rheological parameters are used to define the lipophilic skin moisturizing agent used herein. The viscosity of the lipophilic skin moisturizing agent is represented by consistency (k) and shear index (n). The lipophilic skin moisturizing agents for use herein typically have a consistency (k) ranging from about 5 to about 5,000 poise, preferably from about 10 to about 3,000 poise, more preferably from about 50 to about 2,000 poise, as measured by the Consistency (k) Method hereinafter set forth in the Analytical Methods section. Suitable lipophilic skin moisturizing agents for use herein further have a shear index (n) ranging from about 0.01 to about 0.9, preferably from about 0.1 to about 0.5, more preferably from about 0.2 to about 0.5, as measured by the Shear Index Method hereinafter set forth in the Analytical methods section.

While not being bound by any theory, it is believed that lipophilic skin moisturizing agents having rheology properties other than those defined herein are either too easily emulsified and hence will not deposit, or are too "stiff" to adhere or deposit on to skin and provide a moisturization benefit. In addition, the rheological properties of the lipophilic skin moisturizing agent are also important to user perception. Some lipophilic skin moisturizing agents, on deposition to the skin, are considered too sticky and are not preferred by the user.

In some cases, the lipophilic skin moisturizing agent can also desirably be defined in terms of its solubility parameter, as defined by Vaughan in Cosmetics and Toiletries, Vol. 103, p. 47-69, October 1988. A lipophilic skin moisturizing agent having a Vaughan solubility

Parameter (VSP) from 5 to 10, preferably from 5.5 to 9 is suitable for use in the liquid personal cleansing compositions herein.

A wide variety of lipid type materials and mixtures of materials are suitable for use as the carrier in the antimicrobial personal cleansing compositions of the present invention. Preferably, the lipophilic skin conditioning agent is selected from the group consisting of hydrocarbon oils and waxes, silicones, fatty acid derivatives, cholesterol, cholesterol derivatives, di- and tri-glycerides, vegetable oils, vegetable oil derivatives, liquid nondigestible oils such as those described in U.S. Patents 3,600,186 to Mattson; Issued August 17, 1971 and 4,005,195 and 4,005,196 to Jandacek et al; both issued January 25, 1977, all of which are herein incorporated by reference, or blends of liquid digestible or nondigestible oils with solid polyol polyesters such as those described in U.S. Patent 4,797,300 to Jandacek; issued January 10, 1989; U.S. Patents 5,306,514, 5,306,516 and 5,306,515 to Letton; all issued April 26, 1994, all of which are herein incorporated by reference, and acetoglyceride esters, alkyl esters, alkenyl esters, lanolin and its derivatives, milk tri-glycerides, wax esters, beeswax derivatives, sterols, phospholipids and mixtures thereof. Fatty acids, fatty acid soaps and water soluble polyols are specifically excluded from our definition of a lipophilic skin moisturizing agent.

Hydrocarbon oils and waxes: Some examples are petrolatum, mineral oil micro-crystalline waxes, polyalkenes (e.g. hydrogenated and nonhydrogenated polybutene and polydecene), paraffins, cerasin, ozokerite, polyethylene and perhydrosqualene. Blends of petrolatum and hydrogenated and nonhydrogenated high molecular weight polybutenes wherein the ratio of petrolatum to polybutene ranges from about 90:10 to about 40:60 are also suitable for use as the lipid skin moisturizing agent in the compositions herein.

Silicone Oils: Some examples are dimethicone copolyol, dimethylpolysiloxane, diethylpolysiloxane, high molecular weight dimethicone, mixed C1-C30 alkyl polysiloxane, phenyl dimethicone, dimethiconol, and mixtures thereof. More preferred are non-volatile silicones selected from dimethicone, dimethiconol, mixed C1-C30 alkyl polysiloxane, and mixtures thereof. Nonlimiting examples of silicones useful herein are described in U.S. Patent No. 5,011,681, to Ciotti et al., issued April 30, 1991, which is incorporated by reference.

Di- and tri-glycerides: Some examples are castor oil, soy bean oil, derivatized soybean oils such as maleated soy bean oil, safflower oil, cotton seed oil, corn oil, walnut oil, peanut oil, olive oil, cod liver oil, almond oil, avocado oil, palm oil and sesame oil, vegetable oils and vegetable oil derivatives, coconut oil and derivatized coconut oil, cottonseed oil and derivatized cottonseed oil, jojoba oil, cocoa butter, and the like.

Acetoglyceride esters are used and an example is acetylated monoglycerides.

Lanolin and its derivatives are preferred and some examples are lanolin, lanolin oil, lanolin wax, lanolin alcohols, lanolin fatty acids, isopropyl lanolate, acetylated lanolin, acetylated lanolin alcohols, lanolin alcohol linoleate, lanolin alcohol riconoleate.

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It is most preferred when at least 75% of the lipophilic skin conditioning agent is comprised of lipids selected from the group consisting: petrolatum, blends of petrolatum and high molecular weight polybutene, mineral oil, liquid nondigestible oils (e.g. liquid cottonseed sucrose octaesters) or blends of liquid digestible or nondigestible oils with solid polyol polyesters (e.g. sucrose octaesters prepared from C22 fatty acids) wherein the ratio of liquid digestible or nondigestible oil to solid polyol polyester ranges from about 96:4 to about 80:20, hydrogenated or nonhydrogenated polybutene, microcrystalline wax, polyalkene, paraffin, cerasin, ozokerite, polyethylene, perhydrosqualene, dimethicones, alkyl siloxane, polymethylsiloxane, methylphenylpolysiloxane and mixtures thereof. When as blend of petrolatum and other lipids is used, the ratio of petrolatum to the other selected lipids (hydrogenated or unhydrogenated polybutene or polydecene or mineral oil) is preferably from about 10:1 to about 1:2, more preferably from about 5:1 to about 1:1.

#### E. STABILIZERS

A stabilizer is also included in the liquid antimicrobial personal cleansing compositions herein at a level ranging from about 0.1% to about 10%, preferably from about 0.1% to about 8%, more preferably from about 0.1% to about 5% by weight of the composition.

The stabilizer is used to form a crystalline stabilizing network in the liquid cleansing composition that prevents the lipophilic skin moisturizer agent droplets from coalescing and phase splitting in the product. The network exhibits time dependent recovery of viscosity after shearing (e.g., thixotropy).

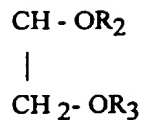
The stabilizers used herein are not surfactants. The stabilizers provide improved shelf and stress stability, but allow the liquid personal cleansing composition to separate upon lathering, and thereby provide for increased deposition of the lipophilic skin moisturizing agent onto the skin. This is particularly true when the cleansing emulsions of the present invention are used in conjunction with a polymeric diamond meshed sponge implement such as that described in Campagnoli; U.S. Patent 5,144,744; Issued September 8, 1992, herein incorporated by reference.

In one embodiment of the present invention, the stabilizer employed in the personal cleansing compositions herein comprises a crystalline, hydroxyl-containing stabilizer. This stabilizer can be a hydroxyl-containing fatty acid, fatty ester or fatty soap water-insoluble wax-like substance or the like.

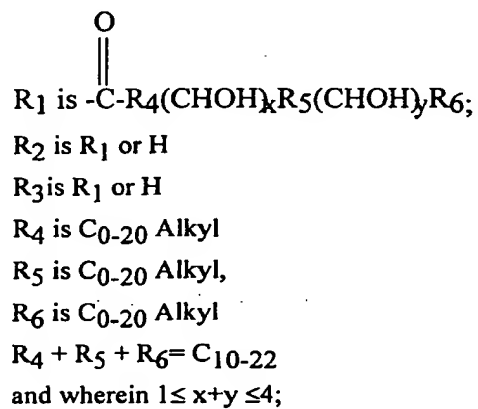
The crystalline, hydroxy-containing stabilizer is selected from the group consisting of:

- (i)  $\text{CH}_2 - \text{OR}_1$

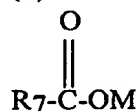
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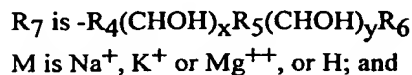
wherein



(ii)



wherein



iii) mixtures thereof;

Some preferred hydroxyl-containing stabilizers include 12-hydroxystearic acid, 9,10-dihydroxystearic acid, tri-9,10-dihydroxystearin and tri-12-hydroxystearin (hydrogenated castor oil is mostly tri-12-hydroxystearin). Tri-12-hydroxystearin is most preferred for use in the emulsion compositions herein.

When these crystalline, hydroxyl-containing stabilizers are utilized in the personal cleansing compositions herein, they are typically present at from about 0.1% to 10%, preferably from 0.1% to 8%, more preferably from 0.1% to about 5% of the liquid personal cleansing compositions. The stabilizer is insoluble in water under ambient to near ambient conditions.

Alternatively, the stabilizer employed in the personal cleansing compositions herein can comprise a polymeric thickener. When polymeric thickeners as the stabilizer in the personal

cleansing compositions herein, they are typically included in an amount ranging from about 0.01% to about 5%, preferably from about 0.3% to about 3%, by weight of the composition. The polymeric thickener is preferably an anionic, nonionic, cationic or hydrophobically modified polymer selected from the group consisting of cationic polysaccharides of the cationic guar gum class with molecular weights of 1,000 to 3,000,000, anionic, cationic, and nonionic homopolymers derived from acrylic and/or methacrylic acid, anionic, cationic, and nonionic cellulose resins, cationic copolymers of dimethyldialkylammonium chloride, and acrylic acid, cationic homopolymers of dimethylalkylammonium chloride, cationic polyalkylene, and ethoxypolyalkylene imines, polyethylene glycol of molecular weight from 100,000 to 4,000,000, and mixtures thereof. Preferably, the polymer is selected from the group consisting of sodium polyacrylate, hydroxy ethyl cellulose, cetyl hydroxy ethyl cellulose, and Polyquaternium 10.

Alternatively, the stabilizer employed in the personal cleansing compositions herein can comprise C10-C22 ethylene glycol fatty acid esters. C10-C22 ethylene glycol fatty acid esters can also desirably be employed in combination with the polymeric thickeners hereinbefore described. The ester is preferably a diester, more preferably a C14-C18 diester, most preferably ethylene glycol distearate. When C10-C22 ethylene glycol fatty acid esters are utilized as the stabilizer in the personal cleansing compositions herein, they are typically present at from about 3% to about 10%, preferably from about 5% to about 8%, more preferably from about 6% to about 8% of the personal cleansing compositions.

Another class of stabilizer which can be employed in the personal cleansing compositions of the present invention comprises dispersed amorphous silica selected from the group consisting of fumed silica and precipitated silica and mixtures thereof. As used herein the term "dispersed amorphous silica" refers to small, finely divided non-crystalline silica having a mean agglomerate particle size of less than about 100 microns.

Fumed silica, which is also known as arced silica, is produced by the vapor phase hydrolysis of silicon tetrachloride in a hydrogen oxygen flame. It is believed that the combustion process creates silicone dioxide molecules which condense to form particles. The particles collide, attach and sinter together. The result of this process is a three dimensional branched chain aggregate. Once the aggregate cools below the fusion point of silica, which is about 1710°C, further collisions result in mechanical entanglement of the chains to form agglomerates. precipitated silicas and silica gels are generally made in aqueous solution. See, Cabot Technical Data Pamphlet TD-100 entitled "CAB-O-SIL® Untreated Fumed Silica Properties and Functions", October 1993, and Cabot Technical Data Pamphlet TD-104 entitled "CAB-O-SIL® Fumed Silica in Cosmetic and Personal Care Products", March 1992, both of which are herein incorporated by reference.

The fumed silica preferably has a mean agglomerate particle size ranging from about 0.1 microns to about 100 microns, preferably from about 1 micron to about 50 microns, and more preferably from about 10 microns to about 30 microns. The agglomerates are composed of ~~aggregates which have a mean particle size ranging from about 0.01 microns to about 15~~ microns, preferably from about 0.05 microns to about 10 microns, more preferably from about 0.1 microns to about 5 microns and most preferably from about 0.2 microns to about 0.3 microns. The silica preferably has a surface area greater than 50 sq. m./gram, more preferably greater than about 130 sq. m./gram, most preferably greater than about 180 sq. m./gram.

When amorphous silicas are used as the stabilizer herein, they are typically included in the emulsion compositions at levels ranging from about 0.1% to about 10%, preferably from about 0.25% to about 8%, more preferably from about 0.5% to about 5%.

A fourth class of stabilizer which can be employed in the personal cleansing compositions of the present invention comprises dispersed smectite clay selected from the group consisting of bentonite and hectorite and mixtures thereof. Bentonite is a colloidal aluminum clay sulfate. See Merck Index, Eleventh Edition, 1989, entry 1062, p. 164, which is incorporated by reference. Hectorite is a clay containing sodium, magnesium, lithium, silicon, oxygen, hydrogen and fluorine. See Merck Index, eleventh Edition, 1989, entry 4538, p. 729, which is herein incorporated by reference.

When smectite clay is employed as the stabilizer in the personal cleansing compositions of the present invention, it is typically included in amounts ranging from about 0.1% to about 10%, preferably from about 0.25% to about 8%, more preferably from about 0.5% to about 5%.

Other known stabilizers, such as fatty acids and fatty alcohols, can also be employed in the compositions herein. Lauric acid and palmitic acid are especially preferred for use herein.

#### F. WATER

Liquid rinse-off antimicrobial cleansing compositions of the present invention comprise from about 35% to about 88.8%, preferably from about 45% to about 80%, more preferably from about 55% to about 75% water.

Liquid rinse-off antimicrobial cleansing compositions of the present invention, preferably have an apparent or neat viscosity of from about 500 cps to about 60,000 cps at 26.7°C, preferably 5,000 to 30,000 cps. The term "viscosity" as used herein means the viscosity as measured by a Brookfield RVTDCP with a spindle CP-41 at 1 RPM for 3 minutes, unless otherwise specified. The "neat" viscosity is the viscosity of the undiluted liquid cleanser.

#### G. PREFERRED OPTIONAL INGREDIENTS

##### Mildness Enhancers

In order to achieve the mildness required of the present invention, optional ingredients to enhance the mildness to the skin can be added. These ingredients include cationic and nonionic

polymers, mildness-enhancing co-surfactants, and mixtures thereof. Polymers useful herein include polyethylene glycols, polypropylene glycols, hydrolyzed silk proteins, hydrolyzed milk proteins, hydrolyzed keratin proteins, guar hydroxypropyltrimonium chloride, polyquats, silicone-polymers and mixtures thereof. Polymers, preferably cationic polymers, are preferably included in the compositions herein at a level of from about 0.1 to about 10% by weight of the composition. Co-surfactants useful herein include nonionic surfactants such as the Genapol® 24 series of ethoxylated alcohols, POE(20) sorbitan monooleate (Tween® 80), polyethylene glycol cocoate and Pluronic® propylene oxide/ethylene oxide block polymers, and amphoteric surfactants such as alkyl betaines and alkyl sultaines. Cosurfactants are typically included in the compositions herein at a level ranging from about 2% to about 70% by weight of the anionic surfactant.

#### H. OTHER OPTIONAL INGREDIENTS

The compositions of the present invention can comprise a wide range of optional ingredients. The CTFA International Cosmetic Ingredient Dictionary, Sixth Edition, 1995, which is incorporated by reference herein in its entirety, describes a wide variety of nonlimiting cosmetic and pharmaceutical ingredients commonly used in the skin care industry, which are suitable for use in the compositions of the present invention. Nonlimiting examples of functional classes of ingredients are described at page 537 of this reference. Examples of these functional classes include: abrasives, anti-acne agents, anticaking agents, antioxidants, binders, biological additives, bulking agents, chelating agents, chemical additives, colorants, cosmetic astringents, cosmetic biocides, denaturants, drug astringents, emulsifiers, external analgesics, film formers, fragrance components, humectants, opacifying agents, plasticizers, preservatives, propellants, reducing agents, skin bleaching agents, skin-conditioning agents (emollient, humectants, miscellaneous, and occlusive), skin protectants, solvents, foam boosters, hydrotropes, solubilizing agents, suspending agents (nonsurfactant), sunscreen agents, ultraviolet light absorbers, and viscosity increasing agents (aqueous and nonaqueous). Examples of other functional classes of materials useful herein that are well known to one of ordinary skill in the art include solubilizing agents, sequestrants, and keratolytics, and the like.

#### II. METHODS OF MANUFACTURE OF RINSE-OFF ANTIMICROBIAL CLEANSING COMPOSITION

The rinse-off antimicrobial personal cleansing compositions of the present invention are made via art recognized techniques for the various forms of personal cleansing products.

#### III. METHODS OF USING THE RINSE-OFF ANTIMICROBIAL CLEANSING COMPOSITION

The rinse-off antimicrobial personal cleansing compositions of the present invention are useful for personal cleansing, especially for cleansing of the hands. Typically, a suitable or effective amount of the cleansing composition is applied to the area to be cleansed. ~~Alternatively, a suitable amount of the cleansing composition can be applied via intermediate~~ application to a washcloth, sponge, pad, cotton ball, puff or other application device. If desired, the area to be cleansed can be premoistened with water. The compositions of the present invention are combined with water during the cleansing process and rinsed-off from the skin. Generally, an effective amount of product to be used will depend upon the needs and usage habits of the individual. Typical amounts of the present compositions useful for cleansing range from about 0.1 mg/cm<sup>2</sup> to about 10 mg/cm<sup>2</sup>, preferably from about 0.6 mg/cm<sup>2</sup> to about 5 mg/cm<sup>2</sup> skin area to be cleansed.

#### ANALYTICAL TEST METHODS

##### CONSISTENCY (k) AND SHEAR INDEX (n) OF THE LIPOPHILIC SKIN MOISTURIZING AGENT

The Carrimed CSL 100 Controlled Stress Rheometer is used to determine Shear Index, n, and Consistency, k, of the lipophilic skin moisturizing agent used herein. The determination is performed at 35°C with the 4 cm 2° cone measuring system typically set with a 51 micron gap and is performed via the programmed application of a shear stress (typically from about 0.06 dynes/sq. cm to about 5,000 dynes/sq. cm) over time. If this stress results in a deformation of the sample, i.e. strain of the measuring geometry of at least 10<sup>-4</sup> rad/sec, then this rate of strain is reported as a shear rate. These data are used to create a viscosity  $\mu$  Vs. shear rate  $\dot{\gamma}$  flow curve for the material. This flow curve can then be modeled in order to provide a mathematical expression that describes the material's behavior within specific limits of shear stress and shear rate. These results were fitted with the following well accepted power law model (see for instance: Chemical Engineering, by Coulson and Richardson, Pergamon, 1982 or Transport Phenomena by Bird, Stewart and Lightfoot, Wiley, 1960):

$$\text{Viscosity, } \mu = k (\dot{\gamma})^{n-1}$$

##### VISCOSITY OF THE LIQUID PERSONAL CLEANSING COMPOSITION

The Wells-Brookfield Cone/Plate Model DV-II+ Viscometer is used to determine the viscosity of the liquid personal cleansing compositions herein. The determination is performed at 25°C with the 2.4 cm° cone (Spindle CP-41) measuring system with a gap of 0.013 mm between the two small pins on the respective cone and plate. The measurement is performed by injecting 0.5 ml of the sample to be analyzed between the cone and plate and rotating the cone at a set speed of 1 rpm. The resistance to the rotation of the cone produces a torque that is proportional to the shear stress of the liquid sample. The amount of torque is read and computed



by the viscometer into absolute centipoise units (mPa's) based on geometric constants of the cone, the rate of rotation, and the stress related torque.

### EXAMPLES

The following examples further describe and demonstrate embodiments within the scope of the present invention. In the following examples, all ingredients are listed at an active level. The examples are given solely for the purpose of illustration and are not to be construed as limitations of the present invention, as many variations thereof are possible without departing from the spirit and scope of the invention.

Ingredients are identified by chemical or CTFA name.

Liquid Handsoap Component	EXAMPLE 1 Weight %	EXAMPLE 2 Weight %
Ammonium Laureth Sulfate	9.5	5.5
Ammonium Lauryl Sulfate	3.2	2.9
Sodium Lauroamphoacetate	5.4	5.6
Citric Acid Anhydrous	6.3	6.3
Triclosan	0.6	0.5
Petrolatum	16.5	12.0
Tri-hydroxystearin	0.15	0.15
Lauric Acid	1.0	1.5
JR30M	0.6	0.1
Sodium Citrate	to pH 3.9	to pH 3.9
Miscellaneous	2.2	1.2
Water	QS	QS

Shower Gel	WEIGHT %	WEIGHT %	WEIGHT %
Component	1	2	3
Sodium or Ammonium Lauryl Sulfate	6.30	3.15	3.15
Sodium or Ammonium Laureth-3 Sulfate	4.20	9.45	9.45
Sodium or Ammonium Lauroamphoacetate	5.25	5.40	5.40

Cocoamide MEA	2.80	0.00	0.00
Citric Acid	6.50	6.50	6.50
Triclosan®	1.00	0.60	0.8
Sodium Citrate	to pH 4	to pH 3.5	to pH 3.9
Soybean Oil	8.00	0.00	0.00
Petrolatum	0.00	16.50	16.5
Dimethicone Emulsion	0.00	0.00	1.00
Trihydroxystearin	0.00	1.0	1.0
Lauric Acid	0.00	1.0	1.0
Palmitic acid	2.20	0.0	0.0
Polyquaternium 10	0.30	0.60	0.30
PEG 6 Caprylic/Capric Glycerides	1.50	0.00	0.00
Miscellaneous	8.28	1.61	1.98
Water	Q.S.	Q.S.	Q.S.
K Value of Anionic Surfactant	< 0.37	< 0.28	< 0.28
Microtox of Anionic Surfactant	< 3	< 3	< 3
Biological Activity (Z) of acid	1.29	1.29	1.29

#### **Procedure for Making Handsoaps and Shower Gels**

##### **1. Handsoap Examples 1 and 2 and Shower Gel Examples 2 and 3**

Add all ingredients except petrolatum, active and perfume together and heat to the point necessary to melt the stabilizer (approximately 190°F for trihydroxystearin). Cool to below 115°F and add active, petrolatum and perfume. Adjust final pH using NaOH or buffer salt. Add remaining water to complete product.

##### **2. Shower Gel Example 1**

Add moisturizing oils and co-surfactants together and heat ingredients to 130-140°F until dissolved. In another container add primary surfactants, acid, buffer salt, preservatives, viscosity builder (salt), and polymer. Heat to 130-140°F until dissolved. Combine two mixtures (or use single mixture if no oils are present) when both are 130-140°F, then begin cooling. When mixture is below 115°F, add, antibacterial active and perfume. Adjust final pH using NaOH or remaining buffer salt. Add remaining water to complete product.

**WHAT IS CLAIMED IS:**

1. A rinse-off antimicrobial cleansing composition comprising:
  - a. from 0.1% to 1% of an antimicrobial active;
  - b. from 8% to 18% of an anionic surfactant;
  - c. from 2% to 12% of a proton donating agent;
  - d. from 1% to 30% of a lipophilic skin moisturizing agent;
  - e. from 0.1% to 4% of a stabilizer; and
  - f. from 35% to 88.8% of water;wherein at least 67% of the anionic surfactant comprises a mixture of Class A surfactants and Class C surfactants and wherein the weight ratio of Class A surfactants to Class C surfactants ranges from 5:1 to 1:2 and wherein the composition is adjusted to a pH of from 3.5 to 4.5.
2. A rinse-off antimicrobial cleansing composition comprising:
  - a. from 0.1% to 1% of an antimicrobial active;
  - b. from 8% to 18% of an anionic surfactant;
  - c. from 0.15% to 2% of salicylic acid;
  - d. from 1% to 30% of a lipophilic skin moisturizing agent;
  - e. from 0.1% to 4% of a stabilizer; and
  - f. from 45% to 90.65% of water;wherein at least 67% of the anionic surfactant comprises a mixture of Class A surfactants and Class C surfactants and wherein the weight ratio of Class A surfactants to Class C surfactants ranges from 5:1 to 1:2 and wherein the composition is adjusted to a pH of from 3.0 to 5.5.
3. A rinse-off antimicrobial cleansing composition according to any of the preceeding claims wherein the antimicrobial active comprises Triclosan®.
4. A rinse-off antimicrobial cleansing composition according to any of the preceeding claims which additionally comprises from 0.1% to 10% of a polymer selected from the group consisting of cationic polymers, nonionic polymers and mixtures thereof.
5. A rinse-off antimicrobial cleansing composition according to any of the preceeding claims which additionally comprises from 20% to 70% by weight of the anionic surfactant of a

mildness-enhancing cosurfactant selected from the group consisting of betaines, lauroamphoacetate, and mixtures thereof.

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6. A rinse-off antimicrobial cleansing composition according to any of the preceeding claims wherein the proton donating agent is an organic acid having a Biological Activity Index, Z, of greater than 0.75.
  7. A rinse-off antimicrobial cleansing composition according to any of the preceeding claims wherein the ratio of the amount of non-anionic surfactants to the amount of anionic surfactant is less than 1:1.
  8. A rinse-off antimicrobial cleansing composition according to any of the preceeding claims wherein the lipophilic skin moisturizing agent comprises petrolatum.
  9. A rinse-off antimicrobial cleansing composition according to any of the preceeding claims wherein the stabilizer comprises from 0.1% to 1.0% of crystalline tri-12-hydroxystearin and 0.5% to 2.0% of a stabilizer selected from the group consisting of lauric acid, lauric alcohol and mixtures thereof.
  10. A method for providing residual effectiveness against Gram negative bacteria comprising the use of a safe and effective amount of the composition of any of the preceeding claims on human skin.
  11. A method for treating acne comprising the use of a safe and effective amount of the composition of any of the preceeding claims on human skin.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/11161

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61K7/50 C11D3/00

According to International Patent Classification(IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K C11D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 29983 A (COLGATE PALMOLIVE CO ;RAMACHANDRAN PALLASSANA N (US); ROBBINS CLAR) 3 October 1996 see claims ---	1-7
A	GB 2 288 811 A (PROCTER & GAMBLE) 1 November 1995 see the whole document ---	1-11
A	WO 95 32705 A (UNILEVER PLC ;UNILEVER NV (NL)) 7 December 1995 see the whole document see page 10, line 25 - page 13, line 16 ---	1-11
A	WO 96 17918 A (RABONE KENNETH LESLIE ;ALLAN ALEXANDER (GB); SHARPLES MARTIN (GB);) 13 June 1996 see the whole document ---	1-11
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search

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## INTERNATIONAL SEARCH REPORT

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	WO 92 18100 A (PROCTER & GAMBLE) 29 October 1992 see the whole document ---	1
A	WO 96 21426 A (PROCTER & GAMBLE) 18 July 1996 see the whole document ---	1
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